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PATENT SPECIFICATION

DRAWINGS ATTACHED

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COMPLETE SPECIFICATION

Drug Packs

I, JOHN RAE, a British subject of 49 Rusholme Road, London, S.W.15, England, do hereby declare the invention for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to drug packs.

The consumption of drugs such as hypnotics, minor tranquillizers and mood-elevators rises annually. This rise is, in part, caused by the inability of patients to cease taking the drugs at the end of a course of treatment involving regular doses of the drugs. The patient may, for example, have come to rely on the action of the drug, e.g. in the case of sleeping-tablets, and, in some cases, the patient may actually have become addicted to the drug. Reliance on, and addiction to the drug caused in this manner is medically undesirable both in terms of the patient's physical fitness, and his mental health.

It is not always practical to reduce such a patient's dose of a drug simply by giving him fewer tablets. In some cases such direct action may even cause a worsening in the patient's overall condition. One method of reducing a patient's intake of an active drug is to replace it gradually by a less-active drug or even in-active (placebo) dummy. As an example of the former case, a doctor can usually safely reduce the morphine intake of a patient who has been regularly taking this drug by gradually replacing the morphine by codeine. Further, it is known that, in many cases, a patient regularly taking a drug such as a hypnotic or tranquilizer has difficulty in detecting when an active drug is replaced by a placebo. Thus, it is possible to some extent to reduce a patient's drug intake by substituting placebos for active tablets without the patient's knowledge. This latter approach is particularly effective where a patient is not

addicted to a drug, but is, to some extent psychologically reliant on the drug.

It is clearly desirable that substitution of less active or placebo compositions for active drugs should take place in a controlled manner. It would be unsatisfactory, for example, simply to give a patient a bottle of tablets containing 50% active and 50%, e.g., placebo tablets because it would be uncertain in what order the patient would consume the tablets. Thus the patient could over a period take a number of placebos in succession, and no active drug at all, and the sudden drop in active drug consumption might be hazardous to his health. The converse would be equally unsatisfactory.

It is thus desirable that the replacement of active drug by a less active drug or a placebo be carefully controlled by the doctor so that he can be certain that a patient is receiving a predetermined and regular ratio of less active drugs or placebos to active drugs.

This invention provides a drug strip-pack comprising a plurality of unit dosages of each of at least two different pharmaceutical compositions, the said different compositions being either (1) active compositions and placebos or (2) active compositions and less active compositions of the same drug, the said unit dosages being packed, by sealing within wrapping, in a single row or in a plurality of parallel rows in such a way that they are adapted to be removed in a predetermined order, such that the frequency of the placebos or less active compositions (as the case may be) is either (a) substantially the same throughout the pack or (b) less among that sixth of the unit dosages adapted to be removed first from the said pack than among that sixth adapted to be removed last, and increases regularly through each sixth of the unit dosages.

A patient receiving a pack containing active and less active or placebo compositions consumes the tablets in a regular pattern, and

[Price 5s. 0d.]

in so doing regularly receives a less active drug or placebo instead of an active drug. When the pack contains active compositions and placebos, the ratio of active to placebo composition in the drug pack is preferable 4:1 to 1:4, a ratio of 1:2 to 2:1 being particularly preferred. Alternatively, and especially when the drug pack contains a relatively large number of, for example, tablets, which are to be taken by the patient over a fairly long period of time, the pack can be arranged to ensure that the patient gradually receives fewer and fewer active tablets as the course proceeds. For example, a pack of 60 tablets could be arranged so that in the first 10 days the patient receives 8 active tablets, in the succeeding 10 days 7 active tablets, and so on, until in the final 10 days, the patient receives only 3 active tablets. The rate of decrease of active tablets throughout such a pack may vary widely and can, of course, be selected by the doctor to suit the patient's condition.

The compositions useful in the drug packs of this invention includes especially lozenges, tablets, pills, capsules, and also phials for injection. The term "active drug" includes both physiologically and chemotherapeutically active drugs, and more especially drugs liable to cause habituation, e.g. analgesics, tranquillizers, hypnotics, mood-elevators, and sedative drugs, e.g. quinalbarbitone.

It is, of course, highly desirable (where relevant drug regulations permit) that the patient should be unable in any way to distinguish between the active and less active or placebo compositions before consumption, i.e. that the compositions should be "superficially identical". Thus, the less active or placebo composition should be identical to the active tablet in size, colour, shape and taste. Suitable placebos are, in general, available commercially, and are used in the testing of drugs prior to marketing.

In one embodiment, the invention comprises a strip-pack containing a number of tablets, e.g. 20, each tablet in the pack being identified by a number beside it on the wrapping material. A predetermined number of the tablets are active, and the rest placebos or less-active tablets. The patient is given the pack and instructed to take the tablets in the order indicated. Thus, if a patient takes one tablet per day, it can be arranged that on every 3rd day he takes a placebo or less-active tablet and on the other days an active drug, by placing the placebo or less-active tablets in the pack in positions 3, 6, 9, 12, 15 and 18.

Such a strip-pack is illustrated in the accompanying drawings, wherein Figure 1 illustrates part of the strip-pack comprising two sheets of wrapping (1, 2) sealed together, and

containing six tablets (3). On one face of the pack by each tablet, there is a number (4) indicating the order in which the tablets are to be consumed. The tablets are packed separately to enable one tablet to be conveniently removed whilst the others remain in place. Scored lines may be provided, e.g. in the manner shown in the drawing (5), to facilitate this.

Figure 2 illustrates a similar strip-pack containing a single row of tablets. The numerals have the same significance as in Figure 1. In order to ensure the removal of, e.g. the tablets in a specific order, this strip-pack may be rolled into a spiral, from which tablets may only be conveniently removed at the free end. In this case, the numbers (4) on the pack beside each tablet are not necessary. It is sometimes advantageous that the tablets in a pack are not numbered, but are arranged to be conveniently available only in a certain predetermined order, (as, e.g., in the spiral strip-pack) since a patient may come to realise that e.g. the placebo or less-active tablets numbered 3, 6, 9 . . . are not as effective as the other tablets, and may consequently not take these tablets.

WHAT I CLAIM IS:—

1. A drug strip-pack comprising a plurality of unit dosages of each of at least two different pharmaceutical compositions, the said different compositions being either (1) active compositions and placebos or (2) active compositions and less active compositions of the same drug, the said unit dosages being packed, by sealing within wrapping, in a single row or in a plurality of parallel rows in such a way that they are adapted to be removed in a predetermined order, such that the frequency of the placebos or less active compositions (as the case may be) is either (a) substantially the same throughout the pack or (b) less among that sixth of the unit dosages adapted to be removed last, and increases regularly through each sixth of the unit dosages.

2. A drug pack as claimed in claim 1, in which the active composition is an analgesic, tranquilizer, hypnotic, mood-elevator, or sedative.

3. A drug pack as claimed in claim 1 or 2, in which the compositions are active composition and placebo in a ratio of 1:4 to 4:1, and the frequency of the placebo is constant throughout the pack.

4. A drug pack as claimed in claim 3, in which the ratio is 1:2 to 2:1.

5. A drug pack as claimed in any of the preceding claims, in which the compositions are superficially identical.

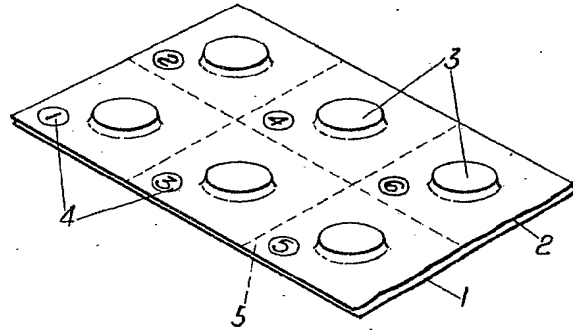
6. A drug pack as claimed in any of claims 1 to 5, in which the compositions are in the form of tablets, pills, lozenges or capsules.

7. A drug pack as claimed in claim 1,
substantially as hereinbefore described with
reference to the accompanying drawings.

8. A drug pack as claimed in claim 1, sub-
5 stantially as described.

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Fig. 1.*Fig. 2.*